

REMARKS

Claim 1 was pending. Claim 1 has been amended, claims 2-14 have been canceled, and new claims 15-22 are added. No new matter is added. Applicants respectfully request entry of the amendments, and reconsideration of the rejections. Support for the amending language may be found in the originally filed claims, and in the specification, particularly at paragraphs 50-55.

The present claims have been rejected under 35 U.S.C. 112, first paragraph. Applicants respectfully submit that one of skill in the art could readily have practiced the present invention as claimed.

The identification of small organic molecule inhibitors is straightforward for one of skill in the art when provided with a complete polypeptide sequence, coding sequences and methods of expressing the polypeptide, and useful biological assays, such as the kinase activity of ILK; and the various biological assays provided in the priority documents. The level of experimentation to identify specific inhibitors is routine, and readily performed by one of ordinary skill in the art.

Practitioners in the chemical and molecular biology arts frequently engage in extensive modification of reaction conditions and complex and lengthy experimentation where many factors must be varied to succeed in performing an experiment or in producing a desired result. The Federal Circuit has found that such extensive experimentation is not undue in the molecular biology arts. For example, the court concluded that extensive screening experiments, while being voluminous, were not undue in view of the art, which routinely performs such long experiments.¹

With respect to the small organic molecules described by Anderson or Zhang, these documents demonstrate that one of skill in the art can readily identify a number of useful molecules for inhibition of ILK, using methods as set forth in the present application. Further, the application provides a specific example of how an inhibitor of ILK is useful in the treatment of psoriasis.

With respect to the breadth of the claims, the breadth is commensurate with the scope of the invention in light of what was previously known. It is believed that the applicant is entitled to this scope for this reason. Withdrawal of the rejection is requested.

Claim 1 has been rejected under 35 U.S.C. 112, second paragraph as indefinite in the recitation of the term "specifically inhibits". Applicants have amended the claim to delete the term. In view of the above amendments, withdrawal of the rejection is requested.

¹ *Hybritech v. Monoclonal Antibodies, Inc.* 231 USPQ 81 (Fed. Cir. 1986)

Claims 1 and 13 have been rejected under 35 U.S.C. 102(b) as anticipated by Bonjouklian *et al.*, U.S. Patent no. 5,378,725.

The invention is based on the finding that the integrin linked kinase (ILK) is clearly correlated with the severity of psoriatic lesions, as shown in Figures 1 and 2. Prior to the instant invention it was unknown whether the activity or expression levels of ILK were altered in the specific human pathologic states resulting from psoriasis. Psoriasis is a complex inflammatory autoimmune condition characterized by an abnormal activation of skin T lymphocytes, dermal and epidermal infiltration by various types of leukocytes, hyper-proliferation of keratinocytes and pronounced angiogenic activity within the dermal vasculature.

As shown in Figure 1, a low level of ILK expression is seen in normal keratinocytes, and little or no ILK staining occurs in the dermal vascular endothelium. In contrast, staining for ILK was found to be highly intense for the hyper-proliferative keratinocytes within psoriatic plaques. Further, some of the inflammatory cells present within the dermal region stained positively for ILK. Overall, in contrast to normal skin, ILK was expressed at much higher levels within the epidermal and dermal regions within skin plaques of patients with psoriasis.

The present claims have been amended to recite the treatment of psoriasis, where the expression of ILK correlates with the severity of psoriasis. Such analysis of ILK is not taught or suggested by the cited reference. In view of the above amendments and remarks, withdrawal of the rejection is requested.

Claims 1 and 13 have been rejected under 35 U.S.C. 102(e) as anticipated by Zhang *et al.* (U.S. Patent no. 6,214,813). Applicants respectfully submit that Zhang *et al.* fails to teach the specific analysis of psoriasis as set forth in the present claims.

The present claims have been amended to recite the treatment of psoriasis, where the expression of ILK correlates with the severity of psoriasis. Such analysis of ILK is not taught or suggested by the cited reference. In view of the above amendments and remarks, withdrawal of the rejection is requested.

Applicants respectfully state herein that Zhang *et al.* is commonly owned with the present application. Although Zhang has not been cited under 35 U.S.C. 103, should such a rejection arise in the future, under 35 U.S.C. 103(c) (1) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the claimed invention was made, owned by the same person or subject to an obligation of assignment to the same person.

The Zhang *et al.* patent is assigned of record to Kinetek Pharmaceuticals, Inc. As evidenced by the attached certificate of Certificate of Amalgamation, Kinetek and QLT are merged, and thus there is a common assignee between the present case and the cited art.

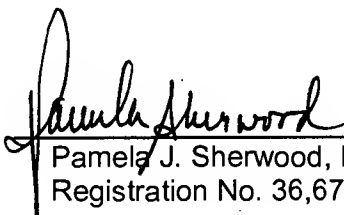
CONCLUSION

Applicants submit that all of the claims are now in condition for allowance, which action is requested. If the Examiner finds that a Telephone Conference would expedite the prosecution of this application, he is invited to telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any other fees under 37 C.F.R. §§ 1.16 and 1.17 which may be required by this paper, or to credit any overpayment, to Deposit Account No. 50-0815, order number KINE-001CIP5.

Respectfully submitted,

Date: November 4, 2005

By: 
Pamela J. Sherwood, Ph.D.
Registration No. 36,677

BOZICEVIC, FIELD & FRANCIS LLP
1900 University Avenue, Suite 200
East Palo Alto, CA 94303
Telephone: (650) 327-3400
Facsimile: (650) 327-3231



EXHIBIT 1 page 1 of 2



**BRITISH
COLUMBIA**

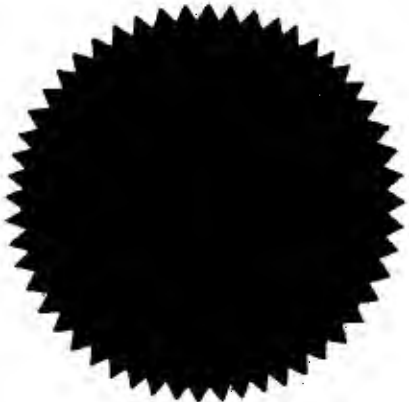
Ministry of Finance
Corporate and Personal
Property Registries

Number: BC0698743

CERTIFICATE OF AMALGAMATION

BUSINESS CORPORATIONS ACT

I Hereby Certify that QLT INC., incorporation number BC0225894 and KINETEK PHARMACEUTICALS, INC., incorporation number C0698658 were amalgamated as one company under the name QLT INC. on July 1, 2004 at 12:01 AM Pacific Time.



Issued under my hand at Victoria, British Columbia

On July 1, 2004

JOHN S. POWELL
Registrar of Companies
Province of British Columbia
Canada

CANADA

PROVINCE OF BRITISH COLUMBIA

TO WIT:

) TO ALL TO WHOM THESE PRESENTS

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) MAY COME BE SEEN OR KNOWN:

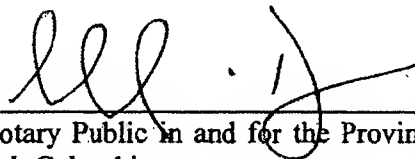
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**IN THE MATTER OF THE AMALGAMATION OF QLT INC. and KINETEK
PHARMACEUTICALS, INC.**

I, R. HECTOR MACKAY-DUNN, a Notary Public by Royal authority appointed, residing in the City of Vancouver, in the Province of British Columbia, do certify and attest that the paper writings hereto annexed, is a true copy of the original document produced to me and purporting to be a copy of the Certificate of Amalgamation issued by the Registrar of Companies on July 1, 2004 respecting the amalgamation of QLT Inc. and Kinetek Pharmaceuticals, Inc., the said copy having been compared by me with the said original document, an act whereof being requested I have granted under notarial form and seal of office to serve and avail as occasion may require.

DATED at Vancouver, British Columbia this 17th day of August, 2004.



A Notary Public in and for the Province of
British Columbia

R. Hector MacKay-Dunn, Q.C.
Barrister & Solicitor
Farris, Vaughan, Wills & Murphy
25th Floor, 700 West Georgia St.
Vancouver, BC V7Y 1B3
Telephone: 604-684-9151